

REMARKS

The Examiner's action dated December 23, 2004, has been received, and its contents carefully noted.

In order to advance prosecution, independent claims 7, 45 and 46 have been amended to more clearly define the contribution of the invention over the prior art.

With respect to the amended claims, the rejection presented in section 1 of the Action is respectfully traversed for the reason that the rejected claims, and particularly independent claim 7, define a system that is not disclosed in the applied reference.

The present invention is directed to a system for use in detecting and diagnosing ear related conditions. This system comprises a device capable of illuminating the inside of a patient's ear with multiple wavelengths and detecting reflections of these wavelengths from the illuminated region (i.e., obtaining a spectrum of reflected light); and a processing unit including a spectral analytical instrument in the form of a spectrometer, which receives the spectrum of reflected light and produces data indicative thereof.

As now recited in each of claims 7, 45 and 46, the processing unit produces an analog signal indicative of the received spectrum and is **preprogrammed with certain models capable of analyzing the analog signal to at least one output**

value related to the condition (state) of the ear from normal condition, serous otitis media condition and otitis media condition. This is implemented by analyzing the analog spectral data and converting it to at least one digital value presenting a spectrum vector indicative of a determined state of the ear, processing the spectrum vector by comparing it to at least one predetermined reference value, and applying a classification model to the processed spectrum value to thereby classify the determined state of the ear as being of normal condition or serous otitis media condition or otitis media condition.

Support for the limitations added to the claims will be found in the specification, for example on page 10 lines 15-24 and page 12 lines 4-7.

The applied reference, Burns et al, discloses a technique for determining a parameter of a medium that scatters infrared radiation. This technique is based on the evaluation of the temperature of a medium from a comparison of the reflected infrared radiation with calibrated values of the reflected radiation and temperature.

However, there is no mention in the applied reference of detecting ear conditions and the technique disclosed therein would not be particularly effective for this purpose. Indeed, the determined increase in the temperature of

the ear medium is not necessarily caused by ear disease, but might be caused by some other disease (inflammation) in a patient's body.

Thus, the system and technique disclosed in this reference are clearly different from the invention and the combination of features of amended Claim 7 is not disclosed in the reference.

Firstly, claim 7 is directed to a system for use in detecting and diagnosing ear related conditions. As already pointed out above, there is no disclosure in the applied reference that the system disclosed therein is useful for such purpose. Furthermore, claim 7 defines a processing unit that converts an analog signal to at least one digital value presenting a spectrum vector indicative of a determined state of the ear, processing this spectrum vector by comparing the spectrum vector to at least one predetermined reference value, and applying a classification model to the processed spectrum value to thereby classify the determined state of the ear and generate output data indicative of one of the following ear conditions: normal condition, serious otitis media condition, and otitis media condition. Clearly, since the applied reference does not relate to the detection of ear conditions, it cannot possibly be considered to anticipate any of the above-cited limitations in claim 7.

Claims 8-13 should be considered allowable at least in view of their dependency from claim 7.

The rejection of Claims 7-15, 18-22, 25-32 and 44 under 35 U.S.C. 103(a) as being obvious over Sheehan et al in view of MacKinnon et al, or alternatively in view of Crowley, is also respectfully traversed.

Sheehan et al discloses a portable data collection device for diagnostic image and data collection at a remote location. This technique utilizes an imaging system operable with different wavelengths of incident light to thereby enable a physician, who receives a plurality of such images from a remote location, to choose an optimal image.

Claim 7 is directed to a system including a device capable of obtaining a spectrum of reflected light from an ear of a subject, together with a processing unit having the features already pointed out above. In addition, claim 7 specifies that the processing unit comprises a spectral analytical instrument in the form of a spectrometer.

Sheehan is concerned solely with an imaging system that produces a visible image of a region within the ear. The reference device does not include a spectrometer or any arrangement that produces a spectrum of reflected light. In the explanation of the rejection, it is acknowledged that this reference differs from the claimed invention "in that a

spectrometer is not specifically addressed". This, it is submitted, is a substantial understatement. The fact is that the reference does not mention a spectrometer at all because it is not concerned with obtaining a spectrum and because a spectrometer would be of no use in producing the images with which the reference is concerned. Therefore, in addition to the fact that the reference does not mention a spectrometer, it is clear that there would be no reason to provide the reference device with a spectrometer because it would serve no purpose.

The explanation of the rejection further suggests that a CCD digital camera obtains a spectrum. It is submitted that this is a clearly incorrect characterization of such a camera and that such characterization is inconsistent with the definition of "spectrometer" presented on page 2 of the Action. A spectrometer produces information that indicates the distribution of wavelengths in an image; this is clearly different from the image itself.

Since Sheehan does not disclose a spectrometer, the rejection is further based on MacKinnon, which also does not disclose, to the extent that can be determined by undersigned, a spectrometer. The passages in the MacKinnon specification cited in the explanation of the rejection do not mention a spectrometer. Indeed, that term has not been found anywhere

in the Specification of that reference. While mention is made of "spectroscopy", it appears that this term is used in the reference specification to identify procedures in which optical images are formed from different wavelengths or group of wavelengths. Here again, this is different from the function performed by a spectrometer.

Moreover, neither of these references discloses the features of the processing unit of claim 7, as cited earlier herein.

Finally, even if the further reference, Crowley, that is relied upon in the alternative, discloses spectrometers, none of the applied references provides any disclosure that would suggest that it would be obvious to combine the teachings of those references in the manner to arrive at the present invention. Indeed, there is no reason to believe that the results that were intended by Sheehan or MacKinnon could be achieved through the use of a spectrometer. Furthermore, even if the imaging devices disclosed by Sheehan or MacKinnon were replaced by spectrometers, the resulting system would not have the features of the processing unit defined in claim 7.

The arguments presented above with respect to claim 7 are fully applicable to the presently amended versions of claims 45 and 46.

The rejection presented in section 3 of the Action is traversed at least for the reason that claims 16, 17, 23 and 24 depend from claim 7, while claims 45 and 46 contain limitations similar to those of claim 7.

The further reference relied upon, Mahler, also does not disclose the above-mentioned features. Moreover, this reference also does not mention a spectrometer and simply serves to provide a temperature indication, which is distinctly different from the type of information obtained according to the claimed invention.

In view of the foregoing, it is requested that all of the prior art rejections of record be reconsidered and withdrawn, that the pending claims be allowed and that the Application be found in allowable condition.

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If the above amendment should not now place the application in condition for allowance, the Examiner is requested to call undersigned counsel schedule an interview to resolve any remaining issues.

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C.
Attorneys for Applicant

By 
Jay M. Finkelstein
Registration No. 21,082

JMF:dtb
Telephone No.: (202) 628-5197
Facsimile No.: (202) 737-3528
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